Assembly Bill No. 2679

CHAPTER 828

An act to amend Section 19353 of the Business and Professions Code, and to amend Sections 11362.775 and 11362.9 of the Health and Safety Code, relating to medical marijuana.

[Approved by Governor September 29, 2016. Filed with Secretary of State September 29, 2016.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2679, Cooley. Medical marijuana: regulation: research.

(1) Existing law, the Medical Marijuana Regulation and Safety Act (MMRSA), provides for the licensure of persons engaged in specified activities relating to medical marijuana and establishes other regulatory provisions. That act also requires each licensing authority to prepare and submit to the Legislature an annual report on the authority's activities and post the report on the authority's Internet Web site.

This bill would require the report to also include the number of appeals from the denial of state licenses or other disciplinary actions taken by the licensing authority, the average time spent on these appeals, and the number of complaints submitted by citizens or representatives of cities or counties regarding licensees, as specified.

(2) Existing law authorizes the creation by the University of California of the California Marijuana Research Program, the purpose of which is to develop and conduct studies intended to ascertain the general medical safety and efficacy of marijuana, and if found valuable, to develop medical guidelines for the appropriate administration and use of marijuana.

This bill would specify that the studies may include studies to ascertain the effect of marijuana on motor skills.

(3) Existing law, until one year after the Bureau of Medical Cannabis Regulation posts a notice on its Internet Web site that licensing authorities have commenced issuing licenses pursuant to the MMRSA, exempts cooperatives and collectives who cultivate medical cannabis for qualified patients from criminal sanctions for specified activities related to the growing, sale, and distribution of marijuana.

This bill, during that same period, would exempt collectives and cooperatives that manufacture medical cannabis products from criminal sanctions for manufacturing medical cannabis if the cooperative or collective meets specified requirements, including using specified manufacturing processes and possessing a valid local license, permit, or other authorization.

The people of the State of California do enact as follows:

SECTION 1. Section 19353 of the Business and Professions Code is amended to read:

19353. Beginning on March 1, 2023, and on or before March 1 of each year thereafter, each licensing authority shall prepare and submit to the Legislature an annual report on the authority's activities, in compliance with Section 9795 of the Government Code, and post the report on the authority's Internet Web site. The report shall include, but not be limited to, the following information for the previous fiscal year:

(a) The amount of funds allocated and spent by the licensing authority for medical cannabis licensing, enforcement, and administration.

(b) The number of state licenses issued, renewed, denied, suspended, and revoked, by state license category.

(c) The average time for processing state license applications, by state license category.

(d) The number of appeals from the denial of state licenses or other disciplinary actions taken by the licensing authority and the average time spent on these appeals.

(e) The number of complaints submitted by citizens or representatives of cities or counties regarding licensees, provided as both a comprehensive statewide number and by geographical region.

(f) The number and type of enforcement activities conducted by the licensing authorities and by local law enforcement agencies in conjunction with the licensing authorities or the bureau.

(g) The number, type, and amount of penalties, fines, and other disciplinary actions taken by the licensing authorities.

SEC. 2. Section 11362.775 of the Health and Safety Code is amended to read:

11362.775. (a) Subject to subdivision (d), qualified patients, persons with valid identification cards, and the designated primary caregivers of qualified patients and persons with identification cards, who associate within the State of California in order collectively or cooperatively to cultivate cannabis for medical purposes, shall not solely on the basis of that fact be subject to state criminal sanctions under Section 11357, 11358, 11359, 11360, 11366, 11366.5, or 11570.

(b) A collective or cooperative that operates pursuant to this section and manufactures medical cannabis products shall not, solely on the basis of that fact, be subject to state criminal sanctions under Section 11379.6 if the collective or cooperative abides by all of the following requirements:

(1) The collective or cooperative does either or both of the following:

(A) Utilizes only manufacturing processes that are either solventless or that employ only nonflammable, nontoxic solvents that are generally recognized as safe pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(B) Utilizes only manufacturing processes that use solvents exclusively within a closed-loop system that meets all of the following requirements:

(i) The system uses only solvents that are generally recognized as safe pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(ii) The system is designed to recapture and contain solvents during the manufacturing process, and otherwise prevent the off-gassing of solvents into the ambient atmosphere to mitigate the risks of ignition and explosion during the manufacturing process.

(iii) A licensed engineer certifies that the system was commercially manufactured, safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, including, but not limited to, the American Society of Mechanical Engineers (ASME), the American National Standards Institute (ANSI), Underwriters Laboratories (UL), the American Society for Testing and Materials (ASTM), or OSHA Nationally Recognized Testing Laboratories (NRTLs).

(iv) The system has a certification document that contains the signature and stamp of a professional engineer and the serial number of the extraction unit being certified.

(2) The collective or cooperative receives and maintains approval from the local fire official for the closed-loop system, other equipment, the extraction operation, and the facility.

(3) The collective or cooperative meets required fire, safety, and building code requirements in one or more of the following:

(A) The California Fire Code.

(B) The National Fire Protection Association (NFPA) standards.

(C) International Building Code (IBC).

(D) The International Fire Code (IFC).

(E) Other applicable standards, including complying with all applicable fire, safety, and building codes in processing, handling, and storage of solvents or gasses.

(4) The collective or cooperative is in possession of a valid seller's permit issued by the State Board of Equalization.

(5) The collective or cooperative is in possession of a valid local license, permit, or other authorization specific to the manufacturing of medical cannabis products, and in compliance with any additional conditions imposed by the city or county issuing the local license, permit, or other authorization.

(c) For purposes of this section, "manufacturing" means compounding, converting, producing, deriving, processing, or preparing, either directly or indirectly by chemical extraction or independently by means of chemical synthesis, medical cannabis products.

(d) This section shall remain in effect only until one year after the Bureau of Medical Cannabis Regulation posts a notice on its Internet Web site that the licensing authorities have commenced issuing licenses pursuant to the Medical Cannabis Regulation and Safety Act (Chapter 3.5 (commencing with Section 19300) of Division 8 of the Business and Professions Code).

(e) This section is repealed one year after the date upon which the notice is posted pursuant to subdivision (d).

SEC. 3. Section 11362.9 of the Health and Safety Code is amended to read:

11362.9. (a) (1) It is the intent of the Legislature that the state commission objective scientific research by the premier research institute of the world, the University of California, regarding the efficacy and safety of administering marijuana as part of medical treatment. If the Regents of the University of California, by appropriate resolution, accept this responsibility, the University of California shall create a program, to be known as the California Marijuana Research Program.

(2) The program shall develop and conduct studies intended to ascertain the general medical safety and efficacy of marijuana and, if found valuable, shall develop medical guidelines for the appropriate administration and use of marijuana. The studies may include studies to ascertain the effect of marijuana on motor skills.

(b) The program may immediately solicit proposals for research projects to be included in the marijuana studies. Program requirements to be used when evaluating responses to its solicitation for proposals, shall include, but not be limited to, all of the following:

(1) Proposals shall demonstrate the use of key personnel, including clinicians or scientists and support personnel, who are prepared to develop a program of research regarding marijuana's general medical efficacy and safety.

(2) Proposals shall contain procedures for outreach to patients with various medical conditions who may be suitable participants in research on marijuana.

(3) Proposals shall contain provisions for a patient registry.

(4) Proposals shall contain provisions for an information system that is designed to record information about possible study participants, investigators, and clinicians, and deposit and analyze data that accrues as part of clinical trials.

(5) Proposals shall contain protocols suitable for research on marijuana, addressing patients diagnosed with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV), cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The proposal may also include research on other serious illnesses, provided that resources are available and medical information justifies the research.

(6) Proposals shall demonstrate the use of a specimen laboratory capable of housing plasma, urine, and other specimens necessary to study the concentration of cannabinoids in various tissues, as well as housing specimens for studies of toxic effects of marijuana.

(7) Proposals shall demonstrate the use of a laboratory capable of analyzing marijuana, provided to the program under this section, for purity and cannabinoid content and the capacity to detect contaminants.

(c) In order to ensure objectivity in evaluating proposals, the program shall use a peer review process that is modeled on the process used by the National Institutes of Health, and that guards against funding research that is biased in favor of or against particular outcomes. Peer reviewers shall be

selected for their expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the applicants or the topic of an approach taken in the proposed research. Peer reviewers shall judge research proposals on several criteria, foremost among which shall be both of the following:

(1) The scientific merit of the research plan, including whether the research design and experimental procedures are potentially biased for or against a particular outcome.

(2) Researchers' expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the topic of, and the approach taken in, the proposed research.

(d) If the program is administered by the Regents of the University of California, any grant research proposals approved by the program shall also require review and approval by the research advisory panel.

(e) It is the intent of the Legislature that the program be established as follows:

(1) The program shall be located at one or more University of California campuses that have a core of faculty experienced in organizing multidisciplinary scientific endeavors and, in particular, strong experience in clinical trials involving psychopharmacologic agents. The campuses at which research under the auspices of the program is to take place shall accommodate the administrative offices, including the director of the program, as well as a data management unit, and facilities for storage of specimens.

(2) When awarding grants under this section, the program shall utilize principles and parameters of the other well-tested statewide research programs administered by the University of California, modeled after programs administered by the National Institutes of Health, including peer review evaluation of the scientific merit of applications.

(3) The scientific and clinical operations of the program shall occur, partly at University of California campuses, and partly at other postsecondary institutions, that have clinicians or scientists with expertise to conduct the required studies. Criteria for selection of research locations shall include the elements listed in subdivision (b) and, additionally, shall give particular weight to the organizational plan, leadership qualities of the program director, and plans to involve investigators and patient populations from multiple sites.

(4) The funds received by the program shall be allocated to various research studies in accordance with a scientific plan developed by the Scientific Advisory Council. As the first wave of studies is completed, it is anticipated that the program will receive requests for funding of additional studies. These requests shall be reviewed by the Scientific Advisory Council.

(5) The size, scope, and number of studies funded shall be commensurate with the amount of appropriated and available program funding.

(f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.

(g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, marijuana. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

(h) The program shall make every effort to recruit qualified patients and qualified physicians from throughout the state.

(i) The marijuana studies shall employ state-of-the-art research methodologies.

(j) The program shall ensure that all marijuana used in the studies is of the appropriate medical quality and shall be obtained from the National Institute on Drug Abuse or any other federal agency designated to supply marijuana for authorized research. If these federal agencies fail to provide a supply of adequate quality and quantity within six months of the effective date of this section, the Attorney General shall provide an adequate supply pursuant to Section 11478.

(k) The program may review, approve, or incorporate studies and research by independent groups presenting scientifically valid protocols for medical research, regardless of whether the areas of study are being researched by the committee.

(*l*) (1) To enhance understanding of the efficacy and adverse effects of marijuana as a pharmacological agent, the program shall conduct focused controlled clinical trials on the usefulness of marijuana in patients diagnosed with AIDS or HIV, cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition. The program may add research on other serious illnesses, provided that resources are available and medical information justifies the research. The studies shall focus on comparisons of both the efficacy and safety of methods of administering the drug to patients, including inhalational, tinctural, and oral, evaluate possible uses of marijuana as a primary or adjunctive treatment, and develop further information on optimal dosage, timing, mode of administration, and variations in the effects of different cannabinoids and varieties of marijuana.

(2) The program shall examine the safety of marijuana in patients with various medical disorders, including marijuana's interaction with other drugs, relative safety of inhalation versus oral forms, and the effects on mental function in medically ill persons.

(3) The program shall be limited to providing for objective scientific research to ascertain the efficacy and safety of marijuana as part of medical treatment, and should not be construed as encouraging or sanctioning the social or recreational use of marijuana.

(m) (1) Subject to paragraph (2), the program shall, prior to any approving proposals, seek to obtain research protocol guidelines from the National Institutes of Health and shall, if the National Institutes of Health issues research protocol guidelines, comply with those guidelines.

(2) If, after a reasonable period of time of not less than six months and not more than a year has elapsed from the date the program seeks to obtain

guidelines pursuant to paragraph (1), no guidelines have been approved, the program may proceed using the research protocol guidelines it develops.

(n) In order to maximize the scope and size of the marijuana studies, the program may do any of the following:

(1) Solicit, apply for, and accept funds from foundations, private individuals, and all other funding sources that can be used to expand the scope or timeframe of the marijuana studies that are authorized under this section. The program shall not expend more than 5 percent of its General Fund allocation in efforts to obtain money from outside sources.

(2) Include within the scope of the marijuana studies other marijuana research projects that are independently funded and that meet the requirements set forth in subdivisions (a) to (c), inclusive. In no case shall the program accept any funds that are offered with any conditions other than that the funds be used to study the efficacy and safety of marijuana as part of medical treatment. Any donor shall be advised that funds given for purposes of this section will be used to study both the possible benefits and detriments of marijuana and that he or she will have no control over the use of these funds.

(o) (1) Within six months of the effective date of this section, the program shall report to the Legislature, the Governor, and the Attorney General on the progress of the marijuana studies.

(2) Thereafter, the program shall issue a report to the Legislature every six months detailing the progress of the studies. The interim reports required under this paragraph shall include, but not be limited to, data on all of the following:

(A) The names and number of diseases or conditions under study.

(B) The number of patients enrolled in each study by disease.

(C) Any scientifically valid preliminary findings.

(p) If the Regents of the University of California implement this section, the President of the University of California shall appoint a multidisciplinary Scientific Advisory Council, not to exceed 15 members, to provide policy guidance in the creation and implementation of the program. Members shall be chosen on the basis of scientific expertise. Members of the council shall serve on a voluntary basis, with reimbursement for expenses incurred in the course of their participation. The members shall be reimbursed for travel and other necessary expenses incurred in their performance of the duties of the council.

(q) No more than 10 percent of the total funds appropriated may be used for all aspects of the administration of this section.

(r) This section shall be implemented only to the extent that funding for its purposes is appropriated by the Legislature in the annual Budget Act.

O